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09/313,524	05/17/1999	GERHARD HOEFLE	5043-1036 US	4030
69056 7590 08/20/2008 FITZPATRICK CELLA (BRISTOL-MYERS) 30 ROCKEFELLER PLAZA NEW YORK, NY 10112-3800				
EXAMINER				
SOLOLA, TAOFTQ A				
ART UNIT		PAPER NUMBER		
1625				
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08/20/2008		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

**Application No.**

09/313,524

**Applicant(s)**

HOEFLE ET AL.

**Examiner**

Taofiq A. Solola

**Art Unit**

1625

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on 12 June 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☐ Claim(s) 1, 3, 15, 16, 21 and 23-27 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 1, 3, 15, 16 and 23-27 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/C)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_
- Paper No(s)/Mail Date na

Claims 1, 3, 15-16, 21, 23-27 are pending in this application.

Claims 2, 4-14, 17-20, 22, are cancelled.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 3, 15-16, 21, 23-27, are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims lack adequate support in the specification. The amendment to the specification filed 10/30/07 in support of enablement of the instant invention is a new matter and must be withdrawn.

Claims 1, 3, 15-16, 21, 23-27, are rejected under 35 U.S.C. 112, first paragraph, because the specification does not reasonably provide enablement for the compounds. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

"In the context of determining whether sufficient "utility as a drug, medicant, and the like in human therapy" has been alleged, It is proper for the examiner to ask for substantiating evidence unless one with ordinary skill in the art would accept the [compounds and the utilities] as obviously correct." *In re Jolles*, 628 F.2d 1327, 1332 (Fed. Cir. 1980), citing *In re Novak*, 306 F.2d 924 (CCPA 1962); see 340 F.2d 974, 977-78 (CCPA 1965). "A specification disclosure

which contains a teaching of the manner and process of making and using the invention . . . must be taken as in compliance with the enabling requirement of the first paragraph of § 112 unless there is reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support." *In re Brana*, 51 F.3d 1560 (Fed. Cir. 1995), *Id.* at 1566, quoting *Marzocchi*, 439 F.2d 220, 223 (CCPA 1971); *Fiers v. Revel*, 984 F.2d 1164, 1171-72 (Fed. Cir. 1993), quoting *Marzocchi*, 439 F.2d at 223; see also *Armbruster*, 512 F.2d 676, 677 (CCPA 1975); *Knowlton*, 500 F.2d 566, 571 (CCPA 1974); *Bowen*, 492 F.2d 859 (CCPA 1974); *Hawkins*, 486 F.2d 569, 576 (CCPA 1973). Where there is "no indication that one skilled in the art would accept without question [the instant compounds and method of use] and no evidence has been presented to demonstrate that the claimed products do have those effects *Novak*, 306 F.2d at 928, an applicant has failed to sufficiently demonstrate sufficient utility and therefore cannot establish enablement.'" *In re Rasmusson*, 75 USPQ2d 1297 (CAFC 2005). The claimed inventions are not believable for the following reasons:

For rejection under 35 U.S.C. 112, first paragraph, the following factors must be considered. *In re Wands*, 8 USPQ2d 1400, 1404 (CAFC, 1988): The factors to be considered [in making an enablement rejection] have been summarized as a) the breadth of the claims, b) the nature of the invention, c) the state of the prior art, d) the relative skill of those in that art, e) the predictability or unpredictability of the art, f) the amount of direction or guidance presented, g) the presence or absence of working examples, and h) the quantity of experimentation necessary, *In re Rainer*, 146 USPQ 218 (1965); *In re Colianni*, 195 USPQ 150, *Ex parte Formal*, 230 USPQ 546. The breadth of the claims includes epothilones A-D and derivatives thereof, process of making, compositions and methods of use. The nature of the invention is using the compounds as pharmaceuticals.

The original specification and claims (5/17/99) fail to disclose how the derivatives are made. There is a disclosure of obtaining epothilones C-D from a microorganism but no disclosure how the derivatives are obtained from the isolated compounds or how epothilones A and B are de-epoxidized to C and D respectively.

To enable the compounds, amendment to the specification was filed 10/30/07 with reference to WO 97/19086 A (US 6,831,076). Not only is the amendment deemed a new matter, the source was not incorporated by reference in accordance with the MPEP, which states as follows:

A mere reference to another application, publication or patent is not an incorporation of anything therein into the application containing such reference for the purpose of satisfying the requirement of 35 USC 112, first paragraph. *In re de Seversky*, 474 F.2d 671, 177 USPQ 144 (CCPA 1973). Particular attention should be directed to the subject matter and the specific portions of the referenced document where the subject matter being incorporated may be found. MPEP 608.01(p).

If the document is a pending US application: prior to allowance of an application that incorporates essential material by reference to a pending US application, if the referenced application has not been published or issued as a patent, applicant is required to amend the disclosure of the referencing application to include the material incorporated by reference. The amendment must be accompanied by an affidavit or declaration executed by the applicant, or a practitioner representing the applicant, stating the amendment consists of the same material incorporated by reference in the referencing application. MPEP 608.01(p). Also, WO 97/19086, was published in a foreign language and applicant fails to file an English translated copy.

The requirement of 35 USC 112, is not what is known or obvious to one of ordinary skill in the art but a "full, clear, concise, and exact terms as to enable any person skilled in the art to

which it pertains, or with which it is most nearly connected, to make and use the same", *Lookwood v. American Airlines Inc.* 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed Cir. 1997). See also the status above.

In claims 23-27, applicant claims what is done and fails to disclose how the processes are performed. However, a claim must stand alone to define the invention, and incorporation into the claims by reference to the specification or an external source is not permitted. Ex parte Fressola, 27 USPQ 2d 1608, BdPatApp & Inter. (1993). In patent examination, it is essential for claims to be precise, clear, correct, and unambiguous. *In re Zletz*, 893 F.2d 319, 13 USPQ2d 1320 (Fed. Cir. 1989).

Therefore, the specification fails to establish correlation between the disclosure and the claims, and would require undue experiment to make and use the invention.

MPEP 2164.01(a) states, "[a] conclusion of lack of enablement means that, based on the evidence regarding any of the above factors, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation. *In re Wright*, 999 F.2d 1557, 1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993)." That conclusion is clearly justified here. Appropriate correction is required.

### ***Response to Argument***

Applicant's arguments filed 6/12/08 have been fully considered but they are not persuasive. Applicant contends that the amendment filed 10/30/07 is in conformity with 608.01(p). This is not persuasive because applicant fails to "express intent to incorporate by reference", WO 97/19086 (page 3 of the specification) when the application was filed. See MPEP 608.01(p) and 37 CFR 1.57(b)(1). Applicant affirms the incorporation of US 6,831, 076, and that it contains no new matter. This is not persuasive because US Application No.

10/602,770, which matures to US '831, was filed 7/25/03, after the filing date (5/17/99) of the instant application, and therefore cannot be incorporated by reference in this application.

Applicant should note that enablement requirement is an "essential material" and may be incorporated by reference but only by way of an incorporation by reference to a US patent or US patent application publication." See MPEP 608.01(p) and 37 CFR 1.57(c), 1.57(c)(1) to (3).

With reference to the rejection of the claims for lack of enablement, particularly claims 23-27, Applicant argues there is no need to incorporate WO 97/19086, "since a plethora of methods for derivatization were well-known at the time this application was filed." This admission implies claims 23-27 are not applicant's invention. Applicant merely replaces analogous starting material in a well-known process. However, using analogous starting material in a well-known process is *prima facie* obvious. *In re Durden*, 226 USPQ 359 (1985). See also *In re Farkas*, 152 USPQ 109 (1966). "Employing a different starting material in a generally old reaction is *prima facie* obvious. Applicant must show evidence reaction would not be expected to take place or that [the new starting material] would behave in a manner different from that of the reference."

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3, 15-16, 21, 23-27, are rejected under 35 U.S.C. 102(b) as being anticipated by DE 195 42 986.9, which discloses the instant invention on pages 2-7, and claims 1-9.

The compounds of the prior arts are assumed not to have "other major metabolic products produced by *Sorangium Cellulosum*, absent a showing to the contrary. Applicant should note that the state of purity of a product is not a limitation. Something old or obvious does not become new upon discovery of new properties (level of purity), functions or utilities. *In re Best*, supra. Also, intended use (claims 15-16) is not a limitation of a compound or product. *In re Hack*, 114USPQ 161 (CCPA, 1957); *In re Craig*, 90 USPQ 33 (CCPA, 1951); *In re Brenner*, 82 USPQ 49 (CCPA, 1949).

### ***Response to Argument and Affidavit***

Applicant's arguments filed 6/12/08 have been fully considered but they are not persuasive. Applicant asserts that the affidavit filed 6/11/08 antedates DE 195 42 986. This is not persuasive because the rejection over DE 195 42 986 is a statutory bar and cannot be overcome by affidavit. See Rule 1.131(a)(2). Also, the publication date of the prior art was 11/17/95. Applicant also asserts method of use is not claimed in the instant application. This assertion ignores claims 15-16 and therefore not persuasive.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,



however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

***Telephone Inquiry***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Taofiq A. Solola, PhD. JD., whose telephone number is (571) 272-0709. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andres Janet, can be reached on (571) 272-0670. The fax phone number for this Group is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

/Taofiq A. Solola/

Primary Examiner, Art Unit 1625

August 17, 2008